REMARKS

This is intended as a full and complete response to the Final Office Action dated January 24, 2006, having a shortened statutory period for response set to expire on April 24, 2006. Please reconsider the claims pending in the application for reasons discussed below.

Claims 54-68 and 70-75 remain pending in the application and upon entry of this response. Claims 54-68 and 70-75 stand rejected by the Examiner. Claims 69 and 76-82 have been cancelled by Applicant without prejudice. Claims 54, 58, 60, 64, and 72 have been amended to clarify the invention.

Election/Restrictions

Claims 69 and 76-82 were withdrawn by the Examiner as being directed to an invention that is independent or distinct from the originally claimed invention. Applicant has cancelled claims 69 and 76-82 without prejudice. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claim 54 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 29 of copending Application No. 10/514,895, Publication No. US 2005/0170000 A1 to *Walker et al.* (hereinafter *Walker*). The Applicant respectfully traverses the rejection.

The Examiner asserts that although the copending claim does not delineate what materials are soluble in the solvent and anti-solvent, the artisan would understand from the commonly used meaning of the terms solvent and anti-solvent that the solubility in *Walker* should be as recited in the instant claim. The Applicant respectfully disagrees with the Examiner's interpretation of *Walker*.

Contrary to the Examiner's assertion, there is no indication in *Walker* that the solubility disclosed in *Walker* should be as recited in claim 54. In *Walker*, the anti-solvent fluid should be a nonsolvent for the target substance. (See page 6, paragraph

[0062]) This means that the active substance taught by *Walker* is not soluble in the anti-solvent. Therefore, the artisan can not read from *Walker* an active substance that is soluble in the anti-solvent and an oligomeric or polymeric material that is not soluble in the anti-solvent as recited in claim 54.

Therefore, claim 54 and *Walker's* claim 29 are patentably distinct from each other. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 54-56, 58-68 and 70-75 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/01221 (hereinafter *Hanna 1*). The Examiner asserts that *Hanna 1* discloses the subject matter as described in claims 54-56, 58-68 and 70-75. The Applicant respectfully traverses the rejection.

In regards to claim 54, and claims dependent thereon, the Examiner asserts that *Hanna 1* implicitly teaches the operating conditions as claimed regarding the solubilities of the different materials in different solvents. Applicant respectfully disagrees. Claim 54 provides a solution or suspension having a fluid vehicle, an active substance, and an oligomeric or polymeric material. A near-critical or supercritical fluid anti-solvent then disperses and exctracts the fluid vehicle from the solution or suspension, leaving particles of the active substance and the oligomeric or polymeric material. Claim 54 further recites that the active substance is soluble in the near-critical or supercritical fluid anti-solvent. However, in Example 10 of *Hanna 1*, salmeterol xinafoate (the active substance) and hydroxypropylcellulose (the polymeric material) are dissolved in an acetone vehicle. Supercritical CO_2 is then used to disperse the solution and extract the acetone vehicle from the salmeterol xinafoate and hydroxypropylcellulose. In *Hanna 1*, supercritical CO_2 is the antisolvent. Salmeterol xinafoate is not soluble, or has a very low solubility, in supercritical CO_2. Applicant respectfully submits the declaration under 37 CFR § 1.132 of Andreas Kordikowski, Ph.D., reciting estimates of the solubility of salmeterol xinafoate as a mole fraction in supercritical CO_2 which are lower than $X_{(SX)} = 1 * 10^{-8}$. Because the active substance of *Hanna 1*, salmeterol xinafoate, is not soluble in the supercritical CO_2, *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation where the active substance is soluble in the anti-solvent and

the oligomeric or polymeric material is not soluble in the anti-solvent, as recited by claim 54. Withdrawal of the rejection is respectfully requested.

In regards to independent claim 60 and claims dependent thereon, the Examiner has invited Applicant to present evidence that the particles made by the method of *Hanna 1* do not meet the crystallinity requirements of the instant claims. In response, Applicant respectfully submits the declaration under 37 CFR § 1.132 of Andreas Kordikowski, Ph.D. In the declaration, Dr. Kordikowski estimates that the active substance of *Hanna 1*, salmeterol xinafoate, is present with a high degree of crystallinity; most likely, more than 95% of the active substance is present in crystalline form. Thus, *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% w/w and about 100% w/w of the active substance is present in an amorphous form, as recited by claim 60. Having presented sufficient evidence as to the crystallinity of the active substance in *Hanna 1*, Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 54-60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hanna 1* in view of Publication No. U.S. 2004/0071783 A1 to *Hanna et al.* (hereinafter *Hanna 2*). The Applicant respectfully traverses the rejection.

The combination of *Hanna 1* and *Hanna 2* does not teach, show or suggest all the elements of claims 54-60. The Examiner relies on *Hanna 2* for teaching that it is known to use ketoprofen in a process utilizing SEDS, and further states it would have been obvious to one of ordinary skill in the art to use the ketoprofen of *Hanna 2* in the *Hanna 1* SEDS process. However, even after combining *Hanna 2* with *Hanna 1*, the combination does not teach, show, or suggest all the elements of claims 54-60.

In regards to claim 54 and claims dependent thereon, the combination of *Hanna 2* and *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation where the active substance is soluble in the anti-solvent and the oligomeric or polymeric material is not soluble in the anti-solvent. As described above, the active compound of *Hanna 1* is not soluble in the anti-solvent. In addition, the active compound in *Hanna 2*, ketoprofen, is not soluble in the anti-solvent, supercritical

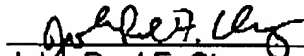
nitrogen. *Hanna 2* discloses that the active substance is for all practical purposes not soluble in the anti-solvent by having a solubility below 10^{-3} mole %, preferably below 10^{-5} mole %. (See, e.g., *Hanna 2* paragraph [0016]) Because both *Hanna 1* and *Hanna 2* teach an active compound which is not soluble in the chosen anti-solvent, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation where the active substance is soluble in the anti-solvent and the oligomeric or polymeric material is not soluble in the anti-solvent, as recited by claim 54 and claims dependent thereon. Withdrawal of the rejection is respectfully requested.

In regards to claim 60, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% and about 100% of the active substance is present in an amorphous as opposed to crystalline form. As described above, the active compound of *Hanna 1*, salmeterol xinafoate, is present with a high degree of crystallinity; most likely, more than 95% of the active substance is present in crystalline form. In addition, the active compounds in *Hanna 2* are also present in a crystalline form. (See, e.g., paragraph [0111], ibuprofene; paragraph [0116] and paragraph [0117], both salicylic acid) Because both *Hanna 1* and *Hanna 2* teach active compounds which are present in mostly crystalline form, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% and about 100% of the active substance is present in an amorphous as opposed to crystalline form, as recited by claim 60. Withdrawal of the rejection is respectfully requested.

In conclusion, the references cited by the Examiner, alone or in combination, do not teach, show, or suggest the invention as claimed.

Having addressed all issues set out in the Final Office Action, Applicant respectfully submits that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,



John-Paul F. Cherry
Registration No. 57,323
PATTERSON & SHERIDAN, L.L.P.
3040 Post Oak Blvd. Suite 1500
Houston, TX 77056
Telephone: (713) 623-4844
Facsimile: (713) 623-4846
Agent for Applicant